REMARKS

Claim 61 and 73-76 are pending and under examination in the above-identified application. Claims 61, 73, 76 and 77 have been amended above to cancel withdrawn embodiments without prejudice.

Regarding 35 U.S.C. § 112, Second Paragraph

Applicants respectfully traverse the rejection of claim 61 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Applicants respectfully submit that this rejection has been rendered moot in view of the amendment to claim 61. Accordingly, removal of the rejection is respectfully requested.

Regarding 35 U.S.C. § 112, First Paragraph (Enablement)

Applicants respectfully traverse the rejection of claims 61 and 73-77 under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

Applicant respectfully maintains that the specification enables the full scope of the claimed invention for the reasons that follow.

In *Amgen, Inc. v. Hoechst Marion Roussel, Inc*, 232 F.3d 905 (Fed.Cir. 2000), the Federal Circuit clarified the enablement requirement:

> The specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without "undue experimentation."

Id. (citing *Genentech, Inc. v. Novo Nordisk, A/S,* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991))

In *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 47 U.S.P.Q.2d 1705 (Fed. Cir. 1998), the Federal Circuit clearly stated that routine experimentation does not constitute undue experimentation:

> The test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Id. (Emphasis added) (citing *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d at 1564, 37 U.S.P.Q.2d at 1623); see also *In re Wands*, 858 F.2d at 736-40, 8 U.S.P.Q.2d at 1403-07.

An Examiner should always look for enabled, allowable subject matter and communicate to applicant what that subject matter is at the earliest point possible in the prosecution of the application. (MPEP 2164.04). Thus, if a rejection is made based on the view that the enablement is not commensurate in scope with the claim, the examiner should identify the subject matter that is considered to be enabled. (MPEP 2164.08).

The Office Action alleges that it is not clear if non-cancerous colon tissue was used in the specification. Applicants respectfully submit that the adequacy of the disclosure is judged from the perspective of one of ordinary skill in the art and that the skilled person would understand that a "normal control" refers to healthy tissue of the corresponding organ. The Examiner is respectfully reminded that "[a] patent need not teach, and preferably omits, what is well known in the art." *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987).

The Office Action cites Stanton et al., British J. Cancer 70:427 (1994), Iehle et al., J. Steroid Biochem. Mol. Biol. 68:189 (1999) and Abbaszadegan et al., Cancer Res. 54:4676 (1994) for the proposition that the expression level of a nucleic acid in cancer is not predictable. None of the cited references discuss currently claimed SEQ ID NO:59, which is disclosed in the specification as being differentially expressed in cancer. Accordingly, it respectfully submitted that these references are not relevant to the specifically recited nucleic acid of the claimed invention and the enablement of the invention.

The Office Action alleges that a difference encompasses an increase and a decrease and asserts it is unpredictable which one, increase or decrease, is predictive of colon cancer. It is respectfully submitted that the specification discloses that SEQ ID NO: 59 is differentially expressed in colon cancer. It would be routine for the skilled person to measure the expression level of SEQ ID NO:59 in colon cancer and normal control tissue to confirm the differential

expression and determine which tissue has increased expression vis-à-vis the other. The Examiner is respectfully reminded that the mere fact that the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be 'undue' in this art. Indeed, great expenditures of time and effort were ordinary in the field of cancer therapies and diagnostics.

In view of the above amendments and remarks, Applicants respectfully request withdrawal of the rejection of claims 61 and 73-77 under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

CONCLUSION

In light of the Amendments and Remarks herein, Applicant submits that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, he is invited to call the undersigned attorney.

Respectfully submitted,

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